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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/766,427	01/18/2001	Linda Hockersmith	IMET0050	7093

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GLENN PATENT GROUP
3475 EDISON WAY
SUITE L
MENLO PARK, CA 94025

EXAMINER	
GITOMER, RALPH J	
ART UNIT	PAPER NUMBER
1651	7

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/766,427	Hockersmith
Examiner	**Art Unit**
Ralph Gitomer	1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Aug 21, 2002* .

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1, 3-5, 8-12, 14, 16, 17, 20-24, 26, 28, 31-33, and 35* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1, 3-5, 8-12, 14, 16, 17, 20-24, 26, 28, 31-33, and 35* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☒ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

The amendment received 8/21/02 has been received and claims 1, 3-5, 8-12, 14, 16, 17, 20-24, 26, 28, 31-33, 35 are currently pending in this application. The amended title is acceptable. This Office Action is made non-final to more thoroughly consider issues remaining under 35 USC 112 that were not completely addressed in the response received 8/21/02. No new references are added to this file.

Claims 1, 4-5, 8-12, 14, 17, 20-24, 26, 28, 31-33, are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In claim 1 and all occurrences, the added feature of ▒said index based on said subject's diabetic status and ease with which said status is controlled▒ is not found in the specification as originally filed.

Claims 1, 3-5, 8-12, 14, 16, 17, 20-24, 26, 28, 31-33, 35 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Each of the following applies in all occurrences.

In claim 35 the preamble is directed to a method of generating a glycemic profile but the claim lacks all the steps required to do so. The last phrase of claim 35, ▒wherein a resulting glycemic profile is minimally correlated to factors other than subject's blood glucose concentration▒ is not understood in context where no other factors appear to be considered. Glycemic profiles are generally correlated to blood glucose concentration and not to other factors. In claims 1 and 14 no units are described which would make such a calculation difficult depending upon the units selected. How would one know how much carbohydrate is determined if there are no units? Further, to perform the calculation one would need to know the starting blood glucose concentration, the target glucose concentration and the index, and how these are obtained or calculated is not set forth. Claim 4 is indefinite as to how the ▒exemplary value▒ is determined. For example, the method of claim 14 ingests a ▒required amount▒ of carbohydrate which is calculated according to the formula in the claim which is based on a value ▒X▒. The value ▒X▒ is somehow obtained/generated after the step of ingesting the ▒required amount▒ of carbohydrate. Thus two unknown variables, CHO and X, are present in the single equation and it is not clear how one of CHO and X is initially determined such that the other of CHO and X can be determined using the formula. Claim 9 is directed to a second amount of carbohydrate but how it is calculated and its function

is not set forth. Claim 12 is not understood as to how the model would be calibrated and what an ▒idealized ant-correlated glycemic profile▒ may be. In claim 14 and all occurrences, Xi is not defined. Claim 16 depends from a canceled claim.

Claims 1, 3-5, 8-12, 14, 16, 17, 20-24, 26, 28, 31-33, 35 are rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling. The selection of a target maximum and a target minimum are critical to determine the rate of change of glucose concentration. Further, how X is calculated is critical or essential to the practice of the invention, but not included in the claim(s), nor is it set forth in the specification. Therefore, the feature is not enabled by the disclosure. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976).

Claims 1, 3-5, 8-12, 14, 16, 17, 20-24, 26, 28, 31-33, 35 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

On page 4 under Summary of the Invention, a point of novelty may be ▒a novel numerical index that quantifies the subject's sensitivity to carbohydrate.▒ This index appears to be critical

to developing an optimal glycemic profile. In the claims this index is represented as X. How X is calculated is not described in such a fashion to enable one of skill in this art to perform the calculation. On page 13 last paragraph bridging to page 14, a description of X and Xi is provided in general terms insufficient to be reproduced. On page 14 Table 4 has no units. A reading of page 15 would appear to imply the point of novelty is optimizing insulin relative to meal times but how to perform such optimization is not taught. It is well known in this art that the type of insulin and dose of insulin will alter the rate of change of glucose level. And the type of food eaten and the quantity of food eaten will affect the rate of change of glucose level.

On page 5 last paragraph, reference blood glucose values are obtained that are uncorrelated to sampling factors such as skin temperature, environmental temperatures, time of day and other blood analytes. How this is performed is not set forth.

On page 6 first paragraph, the invention provides a method of calibrating a noninvasive blood glucose monitor using blood glucose reference values in which correlating to sampling factors previously mentioned is greatly reduced or eliminated. This method is not set forth.

Critical to the invention is the target values such as those set forth in page 8 last paragraph. How these values were selected and their particular significance is not set forth.

On page 9, noninvasive and invasive measurements of blood glucose were made. The significance of performing both is not seen.

On page 9 Table 1 the A1C of the subjects is all relatively low indicating good glucose control. It is understood that a A1C of under 7 generally indicates adequate blood glucose control. How the present invention would relate to those subjects with good glucose control is not seen.

On page 10 Table 2 indicates results of some treatment but what the treatment was has not been set forth. Also, significantly, there was a desired selected maximum and minimum but how the treatment was designed to achieve those values has not been set forth. If the max and min are not at the selected levels, then what? How is this test customized to obtain the desired information? It should be expected that some subjects are more sensitive to a given amount of carbohydrate and insulin than others. On page 11 a more aggressive insulin dosing regimen produced different values. What was this regimen and how was it determined?

On page 12 first paragraph, the rate of change desired is 1.33. How was this determined and what is its significance? Would the rate of change of increase be desired to be the same as rate of change of decrease of blood glucose concentration? On page 12 Table 3 shows results of some unknown treatment for rate of change which varies greatly. What is the significance of this? That some subjects require more carbohydrate or insulin? On page 14 first paragraph, assigning a numerical value to carbohydrate sensitivity is discussed in the absence of glycemic index, glycemic load and many other dietary factors. No mention is made of the type of carbohydrate consumed, only an amount based on generalized factor X.

Now, turning to the remarks in the amendment of 8/21/02, applicant argues the formula of claim 1 is directed to blood glucose concentration and that X has no units. The specification teaches how the model of claim 12 would be practiced. The International Search Authority performed a search of the present claims.

It is the examiner's position that one cannot make a calculation based upon the formula in claim 1 because what the required amount of carbohydrate would be cannot be calculated based on no units of glucose over X which could be anything. As written, it is not seen how the method of claim 12 can be practiced. What the spectroscopic instrumentation based on

idealized ant-correlated glycemic profiles may be and how such profiles may then be used to make a model is not set forth in the claim. No search from the ISA has been provided to the examiner; a copy of any and all searches is hereby requested.

It has been interpreted that the intended invention may be a method of elevating glucose from a starting value to a selected target value by administering an amount of carbohydrate determined by some formula. It is well known in this art that diabetics regularly determine their serum glucose concentration to adjust the dose of insulin and the amount they eat in order to keep their glucose concentration within some selected range. It remains unclear as to how the present invention differs from this well known procedure.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3-5, 8-12, 14, 16, 17, 20-24, 26, 28, 31-33, 35 are rejected under 35 U.S.C. 102(b) as being anticipated by each of Galen, Volpicelli and Liszka-Hackzell.

Galen (5,695,949) entitled "Combined Assay for Current Glucose Level and Intermediate or Long Term Glycemic Control" teaches in column 1, lines 30-35, some patients measure their blood glucose levels up to seven times a day. Based on the observed pattern in the measured glucose levels, the patient and physician together make adjustments in diet, exercise and insulin intake to better manage the disease. In column 4 lines 19-31 various desired levels of glucose concentration are shown.

Volpicelli (Clinical Physiology) entitled "Controlled Oral Glucose tolerance Test: Evaluation of Insulin Resistance With an Insulin Infusion Algorithm That Forces The OGTT Glycaemic Curve Within The Normal Range" teaches in the summary, insulin is infused to keep glucose within the normal range to assess a glycemic curve. On page 33 column 1, a glucose load and insulin are administered according to an algorithm to force the glycemic curve to remain within the normal range of values. On page 40 column 1 last paragraph, parameters are standardized for carbohydrate intake, and time.

Liszka-Hackzel (Computers and Biomedical Research) entitled ▒Prediction of Blood Glucose Levels in Diabetic Patients Using a Hybrid Technique▒ teaches in the summary, balancing the dose of insulin and glucose concentration with an algorithm. On page 132 last paragraph, glucose level is adjusted by insulin dose and diet. Throughout the article, timing is discussed for eating and insulin dosing. See page 142 Fig. 9 shows predicted glucose levels vs. Observed glucose levels.

Claims 1, 3-5, 8-12, 14, 16, 17, 20-24, 26, 28, 31-33, 35 rejected under 35 U.S.C. 102(a) as being anticipated by Brown.

Brown (5,956,501) entitled ▒Disease Simulation System and Method▒ teaches math models, in column 2 first full paragraph, simulating the effect of changes in insulin and diet on the blood glucose profile of a patient. In column 5 a mathematical model to calculate disease control parameter values is described based on time intervals. For a daily rhythm control parameter such as a blood glucose level, the time points are preferably before and after meals. A diabetic patient parameter values include a prescribed dose of insulin, a prescribed intake of carbohydrates, and a prescribed exercise duration. In column 6 last paragraph, parameters include insulin sensitivity. In column 7, the amount of insulin based on sensitivity is used to calculate how much a unit of insulin is expected to lower glucose level. In column 9, amounts of carbohydrates consumed is calculated to obtain an

optimal value. See the claims.

All the features of the claims are taught by each of the above references for the same function.

Regarding claim 3 directed to conventional foods, the above references teach diabetic people eating conventional foods. Regarding claim 12 directed to a calibration method for use in non-invasive methods of blood glucose determination employing spectroscopic instrumentation, the method of Brown is deemed to be inherently usable with known non-invasive methods of glucose determinations.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ralph Gitomer whose telephone number is (703) 308-0732. The examiner can normally be reached on Tuesday-Friday from 8:00 am - 5:00 pm. The examiner can also be reached on alternate Mondays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on (703) 308-4743. The fax phone number for this Art Unit is (703) 308-4556. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-1235. For 24 hour access to patent application information 7 days per week, or for filing applications electronically, please visit our website at

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Ralph Gitomer
Primary Examiner
Group 1651

RALPH GITOMER
PRIMARY EXAMINER
GROUP 1200